

Attorney Docket No.: **DEX-0253**
Inventors: **Sun et al.**
Serial No.: **10/016,157**
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REMARKS

Claim 1-5, 7 and 8 are pending in the instant patent application. Claims 1-5, 7 and 8 have been rejected. Claim 1 has been amended. Support for this amendment is provided in the specification at page 34, lines 9-28. No new matter is added by this amendment. Reconsideration is respectfully requested in light of this amendment and the following remarks.

I. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 1-5, 7 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as the Examiner suggests that basing gene expression analysis solely on a CLASP software program does not immediately identify a real world use. The Examiner suggests that additional evidence is necessary to establish the utility and enablement of the instant claimed invention.

Applicants respectfully disagree.

However, in an earnest effort to advance the prosecution of this case, Applicants are providing herewith a Declaration by Dr. Roberto Macina providing confirming data generated in accordance with teachings of the specification demonstrating that SEQ ID NO:5 is a unique marker for colon cancer. Specifically, Dr.

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Macina's Declaration provides data from experiments measuring relative expression levels for SEQ ID NO:5 by Quantitative Polymerase Chain Reaction (QPCR) in cancerous, normal-adjacent and normal tissues (See paragraphs 4 and 5 of Dr. Macina's Declaration). Procedures for QPCR are described in detail in the instant specification at page 42, line 31 through page 43, line 19, page 96, lines 5-11, and Example 2 at pages 121-124 (also see paragraph 5 of Dr. Macina's Declaration). As shown in the expression table attached to Dr. Macina's Declaration, also summarized in paragraph 6 of Dr. Macina's Declaration, expression levels of SEQ ID NO:5 are higher in cancer samples when compared with all the normal tissue and normal adjacent tissue for colon cancer. Further, as also discussed in paragraph 7 of Dr. Macina's Declaration, the specificity and sensitivity of SEQ ID NO:5 for colon cancer is at least as high as other markers currently approved and used for diagnosis of various cancers. Accordingly, these data, generated in accordance with teachings provided in the instant specification, for example at page 42, line 31 through page 43, line 19, page 96, lines 5-11, and Example 2 at pages 121-124 provide additional supporting evidence that SEQ ID NO:5 is useful as a unique marker for colon cancer.

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Withdrawal of this rejection under 35 U.S.C. § 101 and 35 U.S.C. 112, first paragraph, is therefore respectfully requested.

II. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - written description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the invention was filed, had possession of the claimed invention. In particular, the Examiner suggests that part (c) of claim 1 relating to nucleotides with 99.5% identity could also contain sequences including the entire length of SEQ ID NO:5 plus up to 0.5% of additional sequence on either end of SEQ ID NO:5 and fails to meet the written description requirements.

Applicants respectfully disagree.

However, in an earnest effort to advance the prosecution of this case, Applicants have deleted this phrase from the claims, instead stating in accordance with teachings at page 34 of the specification that the nucleic acid molecule comprises a naturally occurring allelic variant of SEQ ID NO:5.

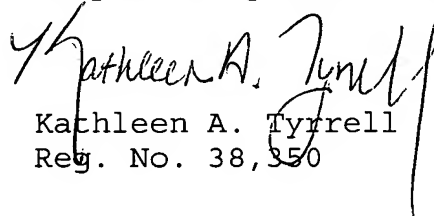
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Withdrawal of this rejection is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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